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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,668	09/07/2000	Jiangchun Xu	210121.484C3	2196

7590 06/17/2002
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EXAMINER

SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/656,668

Applicant(s)

XU ET AL.

Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-13,17-25 and 27-65 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,9-12,14-21,23-25 and 27-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,6-8,13,22 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-4,6-13,17-25 and 27-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment B

Applicants' arguments, filed 04 April 2002, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Declaration - 37 CFR § 1.132

The declaration under 37 CFR 1.132 filed 04 April 2002 is insufficient to overcome the rejection of claims 3, 4, 6-8, 13, 22 and 65 based upon 35 USC § 101 non-statutory subject matter due to lack of utility as set forth in the last Office action because: it is a deficient declaration of evidence due to the lack of clarity of the facts presented. It unclear if the control or normal tissues included that of ovarian to support the conclusion of the utility of SEQ ID NO: 198. It is unclear from the declaration to what the over-expressed ovarian tumorous tissue is compared to, in order to be over-expressed.

In addition the declaration is defective because it was **not** signed.

Claim Rejections - 35 USC § 112/101

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3, 4, 6-8, 13, 22, and 65 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific and substantial asserted utility or a well established utility.

Claims 3, 4, 6-8, 13, 22, and 65 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility, or, alternatively, a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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These rejections are maintained as set forth in the previous office action mailed: 04 December 2001. Unless the tumorous ovarian tissue is compared to normal ovarian tissue, no evidence exists that the sequence would not be detected in normal ovarian tissue as well, or at least at a significant difference than the tumorous ovarian tissue. A biopsy for ovarian cancer diagnosis would not be taken from the trachea to detect ovarian tumorous tissue. The specification and the declaration do not disclose if the sequence is indicative of tumorous tissue that could be detected in any tissue or if it is specific only to ovarian tissue. This is not indicated by the comparison of tumorous ovarian tissue to various normal tissue (not including ovarian). If the sequence is expressed in normal ovarian tissue, the comparison between the tumorous ovarian tissue and normal ovarian tissue is not disclosed. In addition, presuming full-length amplification, no piece or subset is disclosed for design of a suitable primer for the sequence amplification. No statement of the particular or suitable primer to be used for amplification is found within the specification. Concerning the 50 contiguous nucleotides, no utility would result from detection unless the functional or active residues responsible for the ovary tumor-specificity are within that set of 50 bases. The specification does not teach or suggest which residues of the elected sequence, SEQ ID NO: 198, are responsible for the specific analysis or detection process claimed. Thus applicantss arguments are non-persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 6-8, 13, 22, and 65 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained as set forth in the previous office action mailed: 04 December 2001. Applicants argue the metes and bounds of the term “complement” encompass “complete (i.e. 100%) complements”, however these limitations are not within the claim nor are they supported by the specification. Applicants did not point to a page and line of the specification clarifying the metes and bounds of “complements”. In addition, the plurality within “complements of the foregoing polynucleotide” as recited in claims 3, 13, 22 and 65, is

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indicative of more than one complete complement being claimed. If complete complementarity is intended then only one complete complement would exist of the SEQ ID NO: 198. Claims 7 and 8 remain rendered vague and indefinite due to dependency from the indefinite claim 6. Applicants' arguments are non-persuasive.

This rejection is maintained as set forth in the previous office action mailed: 04 December 2001. Applicant's change of terms in claim 65, from "diagnostic" to "detection" did not clarify in any way which diagnostic or detection reagent it is claiming that is capable of being used for both assays. The two assays are different and require different reagents. Applicant's arguments are non-persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 3, 4, 6-8, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by the nucleic acid sequences of GenBank, accession numbers AI023799 and AI307373.

This rejection is maintained as set forth in the previous office action mailed: 04 December 2001. Applicants argue that the claimed polynucleotide must have "at least 90% identity to the entirety of SEQ ID NO: 198" (amendment B, p. 7). However, applicants have not resolved the issue of complementarity which is still within the instant claims. As per option (ii) of claims 3, 6 and 22, the claimed polynucleotide can be a complement of SEQ ID NO: 198 instead of having the minimum 90% identity. Applicants' arguments are non-persuasive.

Conclusion

The arguments are non-persuasive to overcome the rejections. No claim is allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information Disclosure Statement

A copy of the information disclosure statement referenced to by the applicants in their amendment B (p. 3) was unfortunately not found to be included. Please submit another copy.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 14, 2002

Monika B. Sheinberg
Art Unit 1631

MS

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
~~GROUP 1000~~
Art 1631